Virginia Regulatory Town Hall
Agency Background Document
Final Regulation

Agency Name: Department of Rehabilitative Services
VAC Number: § 22 VAC 30-40
Regulation Title: Protection of Human Research Participants
Action Title: Human Research Regulations
Date: January 12, 2000

Summary: The regulation is necessary for the agency to comply with Section 51.5-5.1 of the Code of Virginia. This law mandates the Department and the Board of Rehabilitative Services promulgate regulations to assure the protection of participants in human research conducted or authorized by the Department, the Woodrow Wilson Rehabilitation Center, and any Employment Services Organization or Center for Independent Living (hereinafter referred to as an "institution(s)").

The regulation establishes the policy (§22 VAC 30-40-40) that no human research may be conducted without the voluntary informed consent of the participant or his legally authorized representative and that the informed consent must be documented in writing and supported by the signature of a witness not involved in the research. Human research is defined as any "systematic investigation which utilizes human participants who may be exposed to physical or psychological injury as a consequence of participation and which departs from the application of established and accepted therapeutic methods appropriate to meet the participant's needs" (§22 VAC 30-40-10). Waiver provisions for voluntary informed consent exists in §22VAC 30-40-100.

Each human research study shall be approved by a research review committee. Each institution may establish its own research review committee, may work with other institutions to

establish a single committee, or may use the Department of Rehabilitative Services' established committee. (§22 VAC 30-40-40).

§22 VAC 30-40-50 provides a certification process for institutions seeking to conduct or sponsor human research and the reporting requirements for any violation of the research protocol that leads the research review committee to suspend or terminate the research.

§22 VAC 30-40-50 contains the composition of the research review committee(s), the definition of a committee quorum, and the requirement for the committee(s) and the institution(s) to establish procedures and rules for their operation.

The elements of the committee review is contained in §22 VAC 30-40-70. The elements include consideration to potential benefits and risks and the methodology of the research, the degree of risk for nontherapeutic research, the protection of the rights and welfare of participants, voluntary informed consent, competency of the research investigators, equitable selection criteria for research participants, adherence to other criteria as established by the Board for Rehabilitative Services, and whether appropriate studies in nonhuman systems have been conducted prior to the involvement of human participants. This section also contains a 45 day timeline for consideration of a research proposal by a research review committee, the review notification process, the appeals process, and the reporting requirements.

§22 VAC 30-40-80 provides the criteria by which kinds of research would be exempt from the research review committee review.

§22 VAC 30-40-90 provides an expedited review process for certain kinds of research involving no more than a minimal risk. Under the expedited review process, the committee chairperson

and one or more experienced reviewers designated by the chair from among the members of the committee may carry out the review.

The requirements for informed consent are in §22 VAC 30-40-100. This section also provides the requirements for the research review committee to waive the requirements to obtain some or all informed consent.

§ 22 VAC 30-40-110 contains the requirements for the preparation and maintenance of adequate documentation of the research review committee activities, the retention period for these records, and access to the records for inspection and copying by authorized employees or agents of the department at reasonable times and in a reasonable manner.

§22 VAC 30-40-120 requires each research review committee to submit to the governor, the General Assembly, and the commissioner or his designee at least annually a report on the human research projects reviewed and approved by the committee, including any significant deviations from the proposals as approved.

The role of the department, commissioner, and the board is established in §22 VAC 30-40-130. The section requires the commissioner to establish and maintain records of institutional assurances, annual reports, and summary description of research projects to be reviewed by the board; to review communications from committees reporting violations of research protocols which led to suspension or termination of the research to ensure that appropriate steps have been taken for the protection of human research participants and keep the board informed of all reviews of violations of research protocol; and arrange for the printing and dissemination of copies of these regulations.

§22 VAC 30-40-140 provides that nothing in this chapter shall be construed as limiting in any way the rights of participants in research under regulations promulgated by the board in response to §37.1-84.1 of the Code of Virginia.

§22 VAC 30-40-150 provides that human research at institutions which are subject to policies and procedures for the protection of human participants by any agency of the federal government shall be exempt from this chapter. Such institutions must notify the commissioner and the board annually of their compliance with the policies and regulations of federal agencies.

Basis: § 51.5-5.1 of the Code of Virginia provides the statutory authority to the Board of Rehabilitative Services to promulgate regulations for protection of human participants in research to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research, as defined in § 32.1-162.16.

Purpose: The regulation establishes protocols to approve research proposals involving customers of the department, Woodrow Wilson Rehabilitation Center, any Employment Services Organizations (sheltered workshops) or Centers for Independent Living as mandated by State and Federal law. These protocols will ensure the adequate safeguards for the rights and welfare of human participants and will ensure that such safeguards are consistent with the federal requirements and state law as described in Section 32.1-162 et. seq. of the Code of Virginia. The regulation requires that a human research review committee be established to implement these protocols. Researchers will be required to divulge their research plans to a committee in order to obtain approval for the research. Human participants will be provided with information regarding the action and known consequences of the research. Thus, no participant will be subjected to research against his will.

Substance: This is a new regulation.

Issues: The advantage of this new regulatory provision is that it will ensure that a protocol is in place for protecting human participants of research studies.

There should be no disadvantage to the public.

This same protocol will also provide guidelines for the persons conducting the research. The regulation requires that the researcher devote more time in attending to the rights, safety and welfare of human subjects. It will require more documentation on the part of the researcher and the agency. The protocol could result in certain investigative studies not being implemented due to concern about possible negative effects on the human participants. Therefore, knowledge that could be gathered from these studies may not be available.

These regulatory protocols provide the agency with more control over the research. There is a guideline to follow to ensure that the rights of customers of the agency are protected. However, ensuring the implementation of these regulations will require the agency to assign additional duties to existing staff.

Alternatives:

The statutory requirements mandate the proposed regulatory action. Therefore, the department did not consider alternatives to the regulatory process.

Summary of Public Comment and Agency's Response: No public comments regarding the regulations were received.

Clarity of the Regulation: The regulations have been reviewed and edited by research analysts, policy analysts, the Board of Rehabilitative Services, and the Office of the Attorney General. No comments were provided indicating that the regulations were unclear.

Periodic Review: The agency will initiate a review of the effective regulations in March 2002.

Fiscal Impacts: These regulations apply to approximately 87 employment services organizations, 12 centers for independence and 3 satellite offices, and the Woodrow Wilson Rehabilitation Center and its affiliates. There are no other localities, businesses or entities affected by the proposed regulations. The regulations are not expected to affect employment. Any increase in cost to the regulated entities is expected to be nominal.